Introduction to the Principles and Practice of Clinical Research (IPPCR)

October 18, 2010 – March 15, 2011

All sessions will meet on Monday and Tuesday evenings from 5:00 p.m. to approximately 6:30 p.m. (Eastern Standard Time) in the Lipsett Amphitheater.

Introduction	
Monday, October 18th Session 1	Welcome (30 minutes) John I. Gallin, M.D. Director NIH Clinical Center
	Unit 1: History of Clinical Research: A Merging of Diverse Cultures (30 minutes) John I. Gallin, M.D. Director NIH Clinical Center
Module I, Statistical Methods	
Tuesday, October 19th Session 2	Unit 2: Design of Epidemiologic Studies (1.5 hours) Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM
Monday, October 25th Session 3	Unit 3: Issues in Randomization (1.5 hours) Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM
Tuesday, October 26th Session 4	Unit 4: Measures (1 hour) David Black, Ph.D. Psychologist Pediatric and Development Neuropsychiatry, NIMH
Monday, November 1st Session 5	Unit 5: No lecture
Tuesday, November 2nd Session 6	Unit 6: Participant Selection (1 hour) Catherine Stoney, Ph.D. Program Director Prevention and Population Sciences Program, NHLBI
Thursday, November 4th Session 7	Breakout Session – (1 hour) Title – TBD Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM
Monday, November 8th Session 8	Unit 7: Overview of Hypothesis Testing (1.5 hours) Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM
Tuesday, November 9th Session 9	Unit 8: Secondary Data/Meta Analysis (1 hour) Charles Natanson, M.D. Senior Investigator and Head Anesthesia Section

	Critical Care Medicine Department, CC
Wednesday, November 10th Session 10	Breakout Session – (1 hour) Title – TBD Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM
Monday, November 15th Session 11	Unit 9: Sample Size and Power (1.5 hours) Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM
Tuesday, November 16th Session 12	Unit 10: Conceptual Approach to Survival Analysis (1.5 hours) Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM
Thursday, November 18th Session 13	Breakout Session – (1 hour) Title – TBD Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM
Monday, November 22nd Session 14	Unit 11: Study Development (1.5 hours) Laura Lee Johnson, Ph.D. Statistician Office of Clinical and Regulatory Affairs, NCCAM
Tuesday, November 23rd	RECESS
Monday, November 29th Session 15	Unit 12: Designing and Testing Questionnaires (1 hour) Jack Guralnik, M.D., Ph.D. Chief Epidemiology and Demography Section, NIA
Tuesday, November 30th Session 16	Unit 13: Efficient Clinical Trials (1 hour) John Powers, III, M.D. Senior Medical Scientist, NCI-Frederick
Monday, December 6th Session 18	Unit 14: Research with Vulnerable Participants (45 minutes) David Wendler, Ph.D. Head, Unit on Vulnerable Populations Section on Human Subjects Research, Bioethics Department, CC
	Unit 15: Ethical Principles in Clinical Research (45 minutes) Christine Grady, R.N., Ph.D. Head, Section on Human Subjects Research Acting Chief, Bioethics Department, CC
Module II, Ethical Issues and Regulation of Human Subjects Research	
Tuesday, December 7th Session 19	Unit 1: Legal Issues in Clinical Research (1 hour) Carrie Pottker-Fishel, J.D. Attorney Advisor Office of General Counsel, NIH
Monday, December 13th Session 20	Unit 2: Concepts in the Management of Projects (1 hour) Christopher Breder, M.D., Ph.D. Medical Officer

	Center for Drug Evaluation and Research, FDA
Tuesday, December 14th Session 21	Unit 3: Evaluation of a Protocol Budget (1.5 hours) Margaret Matula, R.N., B.S.N., M.G.A. Director Research and Clinical Trials Anne Arundel Medical Center (Archive video shown)
Monday, December 20th	RECESS
Tuesday, December 21st	RECESS
Monday, December 28th	RECESS
Tuesday, December 29th	RECESS
Monday, January 3rd Session 22	Unit 4: Clinical Research from the Patient's Perspective (1 hour) Susan Butler, B.A., M.A. Former Vice President Ovarian Cancer National Alliance (Due to unforeseen circumstances this will not be a live lecture. The video will be shown from last year).
Tuesday, January 4th Session 23	**Breakout Session:** Mock IRB (2 hours) Jerry Menikoff, M.D., J.D. Director, Office for Human Research Protections Office of Public Health and Science, DHHS
Monday, January 10th Session 24	Unit 5: FDA Product Regulation (1.25 hours) Bette Goldman, R.N., M.P.H. Senior Advisor on Clinical Issues to the Associate Director for Review Management, Center for Biologics Evaluation Research, FDA
Tuesday, January 11th Session 25	Unit 6: The Clinical Researcher and the Media (45 minutes) John Burklow, M.S. Associate Director for Communications Office of Communications and Public Liaison, NIH
	Unit 7: Product Development: Moving from the Bench to the Clinic (45 minutes) Richard Schwartz, Ph.D. Chief Vaccine Production Program Lab Vaccine Research Center, NIAID
Monday, January 17th	FEDERAL HOLIDAY
Tuesday, January 18th Session 26	Unit 8: Data and Safety Monitoring Boards (1 hour) Dennis O. Dixon, Ph.D. Retired NIAID Mathematical Statistician
Module III, Monitoring Patient-Oriented Research and Regulatory Issues	
Monday, January 24th Session 27	Unit 1: Data Management in Clinical Trials (1 hour) Diane St. Germain, R.N., M.S., C.R.N.P. Nurse Consultant Division of Cancer Prevention, NCI
Tuesday, January 25th	Unit 2: Quality Control in Clinical Trials (1 hour)

Session 28	Jack Guralnik, M.D., Ph.D. Chief Epidemiology and Demography Section, NIA
Monday, January 31st Session 29	Unit 3: Quality of Life (1 hour) John Ware, Ph.D. CEO and Chief Science Officer, QualityMetric, Inc.
Tuesday, February 1st Session 30	Unit 4: Scientific Conduct (1 hour) James L. Gulley, M.D., Ph.D., F.A.C.P. Director Clinical Trials Group, Center for Cancer Research, NCI
Monday, February 7th Session 31	Unit 5: NIH Peer Review Process (1 hour) Olivia Bartlett, Ph.D. Chief Research Programs Review, NCI
Module lV, Preparing and Funding a Clinical Research Study	
Tuesday, February 8th Session 32	Unit 1: Design of Case Report Forms (1 hour) Diane St. Germain, R.N., M.S., C.R.N.P. Nurse Consultant Division of Cancer Prevention, NCI
Monday, February 14th Session 33	Unit 2: Information Resources for Clinical Research (1 hour) Josh Duberman, M.L.I.S. Informationist/Research Librarian Medha Bhagwat, Ph.D. Informationist NIH Library
Tuesday, February 15th Session 34	Unit 3: Special Lecture: Human Genome Project and Clinical Research (1 hour) Christopher Austin, M.D. Senior Advisor to the Director for Translation Research, NHGRI
Monday, February 21st	FEDERAL HOLIDAY
Tuesday, February 22nd Session 35	Unit 4: ProtoType and Protocol Mechanics (1 hour) Philip Lightfoot, B.S., B.A. Systems Analysis Department of Clinical Research Informatics, CC
Monday, February 28th Session 36	Unit 5: Technology Transfer (1.5 hours) Bruce Goldstein, J.D. Unit Coordinator Technology Transfer Branch, NCI
Tuesday, March 1st Session 37	Unit 6: Inclusion of Women and Minorities in Clinical Trials (1 hour) Miriam Kelty, Ph.D. Special Volunteer Former Associate Director, Extramural Activities, NIA
Monday, March 7th Session 38	Unit 7: Evaluation of Alternative and Complementary Therapies (1 hour) Marc Blackman, M.D. Associate Chief of Staff for Research and Development Veteran's Administration Medical Center, Washington, DC

Tuesday, March 8th Session 39	Unit 8: Health Disparities Research (1 hour) Kyu Rhee, M.D., M.P.P., FAAP, FACP Chief Public Health Officer Health Resources and Services Administration, DHHS Irene Dankwa-Mullan, M.D., M.P. H. Acting Director Office of Innovation and Program Coordination, NCHMC
Monday, March 14th Session 40	Unit 9: Community-Based Participatory Research (1 hour) Francisco Sy, M.D., Dr PH Director Division of Extramural Activities and Science Programs, NCHMD
Tuesday, March 15th Session 41	TBD

****Schedule subject to change***